K1314G6

SUN NUCLEAR corporation

Your Most Valuable QA & Dosimetry Tools

Section 6 – 510(k) Summary

Provided in accordance with 21 CFR 807.92 (c)

1 General Provisions

Date Prepared:

May 17, 2013

Submitted by:

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AUG 2 0 2013

Contact Person:

Jeff Kapatoes
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Classification Name:

Accelerator, Linear, Medical

Common Name:

Dosimetric Quality Assurance for Patient Specific Radiation Treatment

Proprietary Names:

Model 1177 MapCHECK 2
Model 1220 ArcCHECK

Establishment Registration Number:

1038814

Classification:

Regulation Number: 21 CFR 892.5050
Name: Medical charged-particle radiation therapy system, dosimetric quality control system
Product code: IYE

Predicate Device:

Model Name:	RIT113 Film Analysis System
Common Name:	Film Scanning System
510(k) #	K935928
Manufacturer:	Radiation Imaging Technology
Submitted:	Dec 7, 1993

2 Description and Use:

The Model 1177 MapCHECK 2 and Model 1220 ArcCHECK devices are diode detector arrays that allow the user to perform radiation therapy delivery quality assurance (QA) and dosimetry.

The MapCHECK 2 is a two-dimensional detector array intended to measure radiation dose distribution. The 1527 diode detectors are embedded in polymethyl methacrylate (PMMA) phantom in an array size of 32 cm x 26 cm, with a detector spacing of 7.07 mm and a weight of 7.1 kg. With the provided software installed on the user's computer and connected to the MapCHECK 2 with an 8 pin DIN power/data conduit cable, the software provides the ability for the user to perform QA analysis of a patient's radiation therapy plan prior to treatment.

The ArcCHECK is a three-dimensional cylindrical detector array designed for coherent measurement geometry during rotational treatment delivery. The 1386 diode detectors are embedded in a PMMA phantom on a cylindrical geometric surface with an array size of 21 cm diameter x 21 cm length, with a detector spacing of 10 mm and a weight of 16 kg. This cylindrical array allows for dosimetry measurements to be made from all gantry angles as the therapy beam rotates about the diode array. With the provided software installed on the user's computer and connected to the ArcCHECK with an 8 pin DIN power/data conduit cable, the software provides the ability for the user to perform QA analysis of a patient's radiation therapy plan prior to treatment.

Both MapCHECK 2 and ArcCHECK use the same software application that includes functions for array and dose calibration; measurement and display of the spatial distribution of the dose resulting from delivery of a radiation treatment plan; saving the measurement; importing the treatment planning system (TPS) calculated dose distribution; comparing the measured and planned dose distributions using the analysis methods of gamma or dose difference and distance to agreement (DTA) with user specified analysis criteria; and a report of this analysis that includes percent pass rates.

3 Intended Use Statements:

Sun Nuclear Corporation (SNC) Model 1177 MapCHECK 2 and Model 1220 ArcCHECK have the following intended use:

> Model 1177 MapCHECK 2 is a two-dimensional (2D) radiotherapy beam dosimetry QA system intended for the measurement of radiation dose distributions for the purpose of comparison with a simulated dose distribution in the same phantom geometry as calculated by the treatment planning system (TPS).
>
> Model 1220 ArcCHECK is a three-dimensional (3D) radiotherapy beam dosimetry QA system intended for the measurement of radiation dose distributions for the purpose of comparison with a simulated dose distribution in the same phantom geometry as calculated by the treatment planning system (TPS).

4 Technological Characteristics

The primary technological characteristic of the MapCHECK 2 and the ArcCHECK is the high spatial resolution of the diode detector with an array size and a detector density that enables measurement of dose distributions that have high dose gradients found in radiotherapy deliveries. The spatial resolution of the diode detector is 0.8 mm x 0.8 mm, resulting in very little dose volume averaging over the high dose gradient regions in the plan.

The MapCHECK 2 serves as a 2D phantom with the array of detectors located on a 2D surface embedded at a radiological depth of 2 g/cm^2. The ArcCHECK serves as a 3D

phantom with the detectors located on a 3D cylindrical surface embedded at a radiological depth of 3 g/cm^2.

The predicate device utilizes silver halide film for its radiation detector, which also provides a high spatial resolution and a large area (25 cm x 30 cm) that enables measurement of dose distributions that have high dose gradients found in radiotherapy deliveries.. The film must be used in conjunction with a known phantom to simulate the correct radiologic characteristics. When this film is exposed to radiation from a radiation therapy beam and then developed, the result is that the film exhibits an increased optical density. When a film is exposed by a patient radiation therapy treatment plan, this optical density can then be converted to a dose distribution as would be delivered by that radiation therapy treatment.

5 Performance Data and Comparison with Predicate

The MapCHECK 2 and the ArcCHECK have been tested in non-clinical and clinical settings, and it was shown that these devices perform within their design specifications. Tests that compare known patient treatment plan outputs with that measured by these devices have been conducted; the results were found to have correlation with the actual treatment plan.

Tests were also performed to compare the results of the MapCHECK 2 and the ArcCHECK with film dosimetry devices. It was determined that the results had good correlation.

Performance testing also indicated compliance with relevant electrical safety and EMC standards.

6 Summary

The Model 1177 MapCHECK 2 and the Model 1220 ArcCHECK are deemed substantially equivalent to the predicate device. The intended use, performance testing, safety and effectiveness reviews demonstrate that these devices are as safe, as effective, and perform as well or better than the predicate device. The minor technological differences between the MapCHECK 2, the ArcCHECK and the predicate do not raise new types of safety or effectiveness questions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 20, 2013

JEFF KAPATOES
PRODUCT MANAGER
SUN NUCLEAR CORPORATION
3275 SUNTREE BLVD.
MELBOURNE FL 32940

Re: K131466
Trade/Device Name: MapCheck 2, ArcCheck
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: July 18, 2013
Received: July 19, 2013

Dear Dr. Kapatoes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): k131466

Device Name: Model 1177 MapCHECK2 and Model 1220 ArcCHECK

Indications for Use:

Model 1177 MapCHECK 2 is a two-dimensional (2D) radiotherapy beam dosimetry QA system intended for the measurement of radiation dose distributions for the purpose of comparison with a simulated dose distribution in the same phantom geometry as calculated by the treatment planning system (TPS).

ArcCHECK, Model 1220 is a three-dimensional (3D) radiotherapy beam dosimetry QA system intended for the measurement of radiation dose distributions for the purpose of comparison with a simulated dose distribution in the same phantom geometry as calculated by the treatment planning system (TPS).

Perscription Use ___X___ (Part 21 CFR 801 Subpart D)

OR

Over-The-Counter Use ___ ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k131466